


TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 39042-0037
INTERNATIONAL APPLICATION NO. PCT/GB2004/004740		U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/578692
INTERNATIONAL FILING DATE November 10, 2004		PRIORITY DATE CLAIMED November 10, 2003
TITLE OF INVENTION DRY RECOMBINANT HUMAN ALPHA 1-ANTITRYPSIN FORMULATION		
APPLICANT(S) FOR DO/EO/US Rajiv NAYAR, Mark G. MANNING, Philip J. BARR, Philip PEMBERTON, Ian C. BATHURST, Helen GIBSON		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<div style="margin-left: 20px;">1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.</div> <div style="margin-left: 20px;">2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.</div> <div style="margin-left: 20px;">3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</div> <div style="margin-left: 20px;">4. <input type="checkbox"/> The US has been elected (Article 31).</div> <div style="margin-left: 20px;">5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))<div style="margin-left: 20px;">a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</div><div style="margin-left: 20px;">b. <input checked="" type="checkbox"/> has been communicated by the International Bureau. (copy of PCT/IB/308 attached).</div><div style="margin-left: 20px;">c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</div></div> <div style="margin-left: 20px;">6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).<div style="margin-left: 20px;">a. <input type="checkbox"/> is attached hereto.</div><div style="margin-left: 20px;">b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</div></div> <div style="margin-left: 20px;">7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))<div style="margin-left: 20px;">a. <input checked="" type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</div><div style="margin-left: 20px;">b. <input type="checkbox"/> have been communicated by the International Bureau.</div><div style="margin-left: 20px;">c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</div><div style="margin-left: 20px;">d. <input type="checkbox"/> have not been made and will not be made.</div></div> <div style="margin-left: 20px;">8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</div> <div style="margin-left: 20px;">9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4))</div> <div style="margin-left: 20px;">10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</div>		
Items 11 to 20 below concern document(s) or information included:		
<div style="margin-left: 20px;">11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</div> <div style="margin-left: 20px;">12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</div> <div style="margin-left: 20px;">13. <input checked="" type="checkbox"/> A preliminary amendment.</div> <div style="margin-left: 20px;">14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</div> <div style="margin-left: 20px;">15. <input type="checkbox"/> A substitute specification.</div> <div style="margin-left: 20px;">16. <input type="checkbox"/> A power of attorney and/or change of address letter.</div> <div style="margin-left: 20px;">17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.</div> <div style="margin-left: 20px;">18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</div> <div style="margin-left: 20px;">19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</div> <div style="margin-left: 20px;">20. <input checked="" type="checkbox"/> Other items or information: return postcard</div>		

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <div style="font-size: 1.5em; font-weight: bold;">10/578692</div>		INTERNATIONAL APPLICATION NO. PCT/GB2004/004740		ATTORNEY'S DOCKET NUMBER 39042-0037	
The following fees have been submitted				CALCULATIONS	PTO USE ONLY
21. <input checked="" type="checkbox"/> Basic national fee..... \$300				\$ 300	
22. <input checked="" type="checkbox"/> Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)..... \$100 All other situations..... \$200				\$ 200	
23. <input checked="" type="checkbox"/> Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100 International Search Report prepared and provided to the Office..... \$400 All other situations..... \$500				\$ 500	
TOTAL OF 21, 22 and 23 =				\$ 1000	
<input checked="" type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
16	- 100 = 0	/50 = 0	x \$250	\$ 0	
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims	21 - 20 =	1	x \$ 50	\$ 50	
Independent claims	1 - 3 =	0	x \$200	\$ 0	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360	\$ 0	
TOTAL OF ABOVE CALCULATIONS =				\$ 1050	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					
SUBTOTAL =				\$ 525	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$ 0	
TOTAL NATIONAL FEE =				\$ 525	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$ 0	
TOTAL FEES ENCLOSED =				\$ 525	
				Amount to be refunded:	\$
				Amount to be charged:	\$ 525
a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.					
b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. <u>08-1641</u> in the amount of \$ <u>525</u> to cover the above fees. A duplicate copy of this sheet is enclosed.					
c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>08-1641</u> . A duplicate copy of this sheet is enclosed.					
d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.					
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.					
SEND ALL CORRESPONDENCE TO:					
Heller Ehrman LLP 275 Middlefield Road Menlo Park, CA 94025-3506					
 SIGNATURE					
Leslie Mooi NAME					
37,047 REGISTRATION NUMBER					

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER GJE-7462CXC1
INTERNATIONAL APPLICATION NO. PCT/GB2004/004740	INTERNATIONAL FILING DATE November 10, 2004	U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/578692
TITLE OF INVENTION Dry Recombinant Human Alpha 1-Antitrypsin Formulation		
APPLICANT(S) FOR DO/EO/US Rajiv Nayar, Mark G. Manning, Philip J. Barr, Philip A. Pemberton, Ian C. Bathurst, Helen Gibson		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. 2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. 3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input checked="" type="checkbox"/> The US has been elected (Article 31). 5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input checked="" type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). <u>unsigned</u> 10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). 		
Items 11 to 20 below concern document(s) or information included:		
<ol style="list-style-type: none"> 11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input checked="" type="checkbox"/> A preliminary amendment. 14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A power of attorney and/or change of address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. 18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 		

1AP20 Rec'd PCT/PTO 10 MAY 2006

PTO-1390 (Rev. 07-2005)

Approved for use through 3/31/2007. OMB 0651-0021

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <div style="font-size: 2em; font-weight: bold; margin-top: 5px;">10/578692</div>		INTERNATIONAL APPLICATION NO. PCT/GB2004/004740		ATTORNEY'S DOCKET NUMBER GJE-7462CXC1	
20. Other items or information: Certificate of Mailing by Express Mail Copy of first page of published PCT application WO 2005/047323 A1					
The following fees have been submitted				CALCULATIONS	PTO USE ONLY
21.	<input checked="" type="checkbox"/>	Basic national fee (37 CFR 1.492(a)).....	\$300	\$ 300.00	
22.	<input checked="" type="checkbox"/>	Examination fee (37 CFR 1.492(c))			
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....				\$0	
All other situations.....				\$200	
23.	<input checked="" type="checkbox"/>	Search fee (37 CFR 1.492(b))			
If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....				\$0	
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority.....				\$100	
International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB.....				\$400	
All other situations.....				\$500	
TOTAL OF 21, 22 and 23 =				\$ 900.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
25	- 100 = 0	/50 =	x \$250	\$	
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims	21 - 20 =	1	x \$ 50	\$ 50.00	
Independent claims	1 - 3 =	0	x \$200	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)				+ \$360	\$
TOTAL OF ABOVE CALCULATIONS =				\$ 950.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.				\$	
SUBTOTAL =				\$ 950.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				+	\$
TOTAL NATIONAL FEE =				\$ 950.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				+	\$
TOTAL FEES ENCLOSED =				\$ 950.00	
				Amount to be refunded:	\$
				Amount to be charged	\$

10/578692

Approved for use through 3/31/2007. Form PTO-1390 (Rev. 07-2005)

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- 1AP20 Restoration PTO 10 MAY 2006
- a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 19-0065 in the amount of \$ 950.00 to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0065. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

CUSTOMER NUMBER
23557

May 10, 2006
Date

David Saliwanchik
SIGNATURE

David R. Saliwanchik

NAME

31,794

REGISTRATION NUMBER

10/578692
Patent Application
Docket No. GJE-7462CXC1

1AP20 Rec'd PCT/PTO 10 MAY 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Rajiv Nayar, Mark G. Manning, Philip J. Barr, Philip A. Pemberton,
Ian C. Bathurst, Helen Gibson

Docket No. : GJE-7462CXC1

For : Dry Recombinant Human Alpha 1-Antitrypsin Formulation

Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING BY EXPRESS MAIL (37 CFR §1.10)

Express Mail # **E0543119244US** Date of Deposit: May 10, 2006

I hereby certify that the attached Transmittal Letter to the United States Designated/Elected Office (DO/EO/US) with copies as required for authorization for use of Deposit Account No. 19-0065; Preliminary Amendment; and unsigned Declaration (37 CFR §1.63) and Power of Attorney are being deposited with the United States Postal Service Express Mail Post Office to Addressee service under 37 CFR §1.10 on the date indicated above and are addressed to: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

David Gilland
Name of person mailing paper

David Gilland
Signature